

BASF Corporation

Certified Mail 7099 3400 0015 9379 0255

Return Receipt Requested

BASF

8EHQ-0102-14692's

Sanitized

November 19, 2001

Document Processing Center (TS-790)
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxic Substances
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Ladies and Gentlemen:

Subject: Notice in Accordance with TSCA Section 8(e) –Results of Carcinogenicity Study in C57BL/6J Rj Mice with an Experimental Fungicide. Supplemental to 8EHQ-00-14692

BASF Corporation is submitting further results of a carcinogenicity study in mice with the experimental fungicide Substituted Oximether. This information is supplemental to other results previously submitted on July 30, 2001.

The test substance was administered to groups of 50 male and 50 female C57BL/6J Rj mice at dietary concentrations of 0, 100, 500 and 2,000 ppm. All groups were treated for 18 months. The study was carried out in accordance with the following test guidelines: U.S. EPA § 83-1/83-2 and OECD 451.

Summary of Relevant Results:

In a previous submission on 30-July-2001, a thickening of duodenum wall was reported. In this submission specific histopathological changes in the duodenum are presented as follows:

Sex	Male				Female			
Dose level (ppm)	0	100	500	2,000	0	100	500	2,000
Thickening of mucosa	0	0	0	14	0	0	0	4
Focal hyperplasia	1	0	1	1	0	0	8	6
Adenocarcinoma	0	0	1	4	0	0	0	5

Although these findings occurred only at high dose levels, which are far above any expected human exposure, BASF Corporation understands that the reporting of the study results is in accordance of EPA's policy. Please note that a sanitized version of this letter is enclosed, treating the chemical identity as confidential business information. The confidential chemical name is referred to as "Substituted Oximether". An up-to-date confidentiality substantiation letter is already on file for this product (8EHQ-00-14692).

Very truly yours,

BASF CORPORATION

Edward J. Kerfoot

Edward J. Kerfoot, Ph.D.

Director, Toxicology and Product Regulations

mk
Enc.

RECEIVED
OPTIC
2002 JAN 16 AM 6:28

COMPANY SANITIZED

RECEIVED
OPTIC
2002 FEB -8 AM 9:57

8EHQ-00-14692
890200000495